

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: DUAN et al.

Application Serial No.: To Be Assigned

Art Unit: To Be Assigned

Filed: Concurrently Herewith

Examiner: To Be Assigned

For: Human Parotid Secretory Protein

Atty. Docket: **PF348C1**

Preliminary Amendment Under 37 C.F.R. 1.115

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, Applicants respectfully request entry of the following amendments and remarks. Applicants submit herewith a Version With Markings Showing Changes Made. Please amend the application as follows.

In the Specification

On Page 1, please delete the second full paragraph, beginning "This application claims benefit", in its entirety.

On Page 1, please insert the following paragraph immediately after the Title and before the heading "Field of the Invention":

--This application is a continuation of, and claims benefit under 35 U.S.C. § 120 of United States patent application Serial No. 08/993,529, filed December 18, 1997, which is incorporated by reference in its entirety, which claims benefit under 35 U.S.C. § 119(e) based on U.S. Provisional Application No. 60/034,429, filed December 23, 1996, herein incorporated by reference in its entirety. --

On Page 10, please replace the first full paragraph after the heading "Detailed Description," with the following rewritten paragraph:

--The present invention provides isolated nucleic acid molecules comprising a polynucleotide encoding a hPSP polypeptide having the amino acid sequence shown in Figure 1 (SEQ ID NO:2), which was determined by sequencing a cloned cDNA. The nucleotide sequence shown in Figure 1 (SEQ ID NO:1) was obtained by sequencing the HSGSA61 clone, which was deposited on November 26, 1996 at the American Type Culture Collection, 10801 University Boulevard, Manassas, Virginia 20110-2209, U.S.A., and given accession number ATCC 97811. The deposited clone is contained in the pBluescript SK(-) plasmid (Stratagene, La Jolla, CA).--

On Page 16, please delete the entire paragraph beginning on line 3, and replace with the following amended paragraph:

--In another aspect, the invention provides an isolated nucleic acid molecule comprising a polynucleotide which hybridizes under stringent hybridization conditions to a portion of the polynucleotide in a nucleic acid molecule of the invention described above, for instance, the cDNA clone contained in ATCC Deposit No. 97811. By "stringent hybridization conditions" is intended overnight incubation at 42° C in a solution comprising: 50% formamide, 5x SSC (750 mM NaCl, 75 mM trisodium citrate), 50 mM sodium phosphate (pH 7.6), 5x Denhardt's solution, 10% dextran sulfate, and 20 µg/ml denatured, sheared salmon sperm DNA, followed by washing the filters in 0.1x SSC at about 65° C.--

On Page 36, please replace the first full paragraph, beginning on line 1, with the following rewritten paragraph:

--In the most preferred method, the antibodies of the present invention are monoclonal antibodies (or hPSP protein binding fragments thereof). Such monoclonal antibodies can be prepared using hybridoma technology (Köhler *et al.*, *Nature* 256:495 (1975); Köhler *et al.*, *Eur. J. Immunol.* 6:511 (1976); Köhler *et al.*, *Eur. J. Immunol.* 6:292 (1976); Hammerling *et al.*, in: *Monoclonal Antibodies and T-Cell Hybridomas*, Elsevier, N.Y., (1981) pp. 563-681). In general, such procedures involve immunizing an animal (preferably a mouse) with a hPSP

protein antigen or, more preferably, with a hPSP protein-expressing cell. Suitable cells can be recognized by their capacity to bind anti-hPSP protein antibody. Such cells may be cultured in any suitable tissue culture medium; however, it is preferable to culture cells in Earle's modified Eagle's medium supplemented with 10% fetal bovine serum (inactivated at about 56°C), and supplemented with about 10 g/l of nonessential amino acids, about 1,000 U/ml of penicillin, and about 100 µg/ml of streptomycin. The splenocytes of such mice are extracted and fused with a suitable myeloma cell line. Any suitable myeloma cell line may be employed in accordance with the present invention; however, it is preferable to employ the parent myeloma cell line (SP2O), available from the American Type Culture Collection, Manassas, Virginia. After fusion, the resulting hybridoma cells are selectively maintained in HAT medium, and then cloned by limiting dilution as described by Wands et al. (Gastroenterology 80:225-232 (1981)). The hybridoma cells obtained through such a selection are then assayed to identify clones which secrete antibodies capable of binding the hPSP protein antigen.--

In the Drawings

Please replace the Informal Drawings of Figures 1-3 with Formal Drawings of Figures 1-3 submitted herewith.

In the Claims

Please add the following new claims:

19. (New) An isolated polynucleotide comprising a nucleic acid sequence selected fragment from the group consisting of:

(a) a nucleic acid sequence encoding an amino acid sequence at least 95% identical, using the Bestfit algorithm and default parameters, to a polypeptide of amino acids +1 to +231 of SEQ ID NO:2;

(b) a nucleic acid sequence encoding a polypeptide encoded by the human cDNA contained in ATCC Deposit No. 97811; and

(c) a nucleic acid sequence encoding a polypeptide of at least 30 contiguous amino acids of SEQ ID NO:2.

20. (New) The isolated polynucleotide of claim 19, wherein said nucleic acid sequence is (a).

21. (New) The isolated polynucleotide of claim 20, wherein said amino acid sequence is SEQ ID NO:2.

22. (New) The isolated polynucleotide of claim 20, wherein said nucleic acid sequence is SEQ ID NO:1.

23. (New) The isolated polynucleotide of claim 19, wherein said nucleic acid sequence is (b).

24. (New) The isolated polynucleotide of claim 23, wherein said nucleic acid sequence encodes a mature polypeptide.

25. (New) The isolated polynucleotide of claim 23, wherein said nucleic acid sequence is identical to the human cDNA contained in ATCC Deposit No. 97811.

26. (New) The isolated polynucleotide of claim 19, wherein said nucleic acid sequence is (c).

27. (New) The isolated polynucleotide of claim 26, wherein said nucleic acid sequence encodes at least 50 contiguous amino acids of SEQ ID NO:2.

28. (New) An isolated polynucleotide complementary to the polynucleotide of claim 19.

29. (New) The isolated polynucleotide of claim 19, further comprising a heterologous polynucleotide.

30. (New) The isolated polynucleotide of claim 29, wherein said heterologous polynucleotide encodes a heterologous polypeptide.

31. (New) A method for making a recombinant vector comprising inserting the isolated nucleic acid molecule of claim 19 into a vector.

32. (New) A vector comprising the polynucleotide of claim 19.

33. (New) A host cell comprising the polynucleotide of claim 19, operably associated with a heterologous regulatory sequence.

34. (New) A method for producing a polypeptide, comprising:
(a) culturing a host cell under conditions suitable to produce a polypeptide encoded by the polynucleotide of claim 19; and
(b) recovering the polypeptide from the cell culture.

35. (New) A polypeptide produced by the method of claim 34.

36. (New) A composition comprising the isolated polynucleotide of claim 19.

Remarks

The specification has been amended to perfect the claim to priority of the present application on Page 1, to correct the address and location of the American Type Culture Collection on Pages 10 and 36. The specification has been further amended to correct an obvious typographical error with respect to the correction of the NaCl and trisodium citrate concentrations for 5xSSC disclosed on page 16, line 9 of the specification. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction. *See*, M.P.E.P. § 2163.07. Here, the recognition of the typographical errors, along with the correction of the errors in the specification and claims and in the ingredient amounts listed for 5x SSC is obvious to one skilled in the art; therefore, the correction does not constitute new matter.

5x SSC is a component of many hybridization solutions and is well known in the art. (*See*, e.g., Exhibit A, CURRENT PROTOCOLS IN MOLECULAR BIOLOGY, John Wiley and Sons, N.Y., at page 2.10.7 (1989)). SSC is normally made as a 20x stock solution, and then diluted accordingly for a particular use. Exhibit B shows that a 20x SSC stock solution contains 3 M NaCl and 0.3 M trisodium citrate. (*See*, e.g., Exhibit B, CURRENT PROTOCOLS, at page A.2.5.) To make a 5x SSC solution, the 20x solution must be diluted by a factor of four. Therefore, a 5x SSC solution contains 750 mM NaCl ($3\text{ M} \div 4 = 750\text{ mM}$) and 75 mM trisodium citrate ($0.3\text{ M} \div 4 = 75\text{ mM}$). One skilled in the art would have immediately recognized that the amounts of ingredients listed in the specification for a 5x SSC solution was incorrect. Rather than describing a 5x SSC solution, made up of 750 mM NaCl and 75 mM trisodium citrate, the specification inaccurately listed the ingredient amounts for a 1x solution. The skilled artisan, in recognizing the typographical error, could

have easily adjusted the amount of ingredients described in the specification to properly make a 5x SSC solution.

Therefore, because no new matter will be added to the specification if these typographical errors are corrected, Applicants respectfully request that the amendments to the specification to recite the correct concentrations of sodium chloride and sodium citrate in 5x SSC be entered.

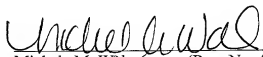
New claims 19-36 have been added to claim additional embodiments of the subject matter of the invention. Newly added claims 19-36 find support throughout the specification as filed, therefore, no new matter has been added by way of this amendment. Claims 1-36 will be pending on entry of the present preliminary amendment.

Conclusion

Applicants respectfully request that the amendments made above be entered and made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to Deposit Account No. 08-3425.

Respectfully submitted,

Dated: December 18, 2001


Michele M. Wales (Reg. No. 43,975)
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MMW/BM/lcc

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parent myeloma cell line (SP2O), available from the American Type Culture Collection, ~~Rockville, Maryland~~ Manassas, Virginia. After fusion, the resulting hybridoma cells are selectively maintained in HAT medium, and then cloned by limiting dilution as described by Wands et al. (Gastroenterology 80:225-232 (1981)). The hybridoma cells obtained through such a selection are then assayed to identify clones which secrete antibodies capable of binding the hPSP protein antigen.

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VIA HAND DELIVERY DECEMBER 18th, 2001

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REQUEST UNDER 37 C.F.R. § 1.821(e)

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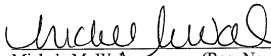
Sir:

The above-identified patent application is a continuation of application Serial No. 08/993,529, filed December 18, 1997. The sequence listing of the instant application is identical to the sequence content of the computer readable sequence listing filed in connection with Application Serial No. 08/993,529, on December 18, 1997.

In accordance with 37 C.F.R. § 1.821(e), please use the computer readable form last-filed in connection with application Serial No. 08/993,529 as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the original and Substitute Sequence Listing is included in the specification of the instant application filed herewith. Applicants hereby certify that the paper copy of the Substitute Sequence Listing filed herewith and the computer readable sequence listing last-filed in connection with application Serial No. 08/993,529 are the same and do not include new matter.

Respectfully submitted,

Dated: 12/18/01


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